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| APPLICATION NO.                       | FILING DATE     | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO.     | CONFIRMATION NO. |
|---------------------------------------|-----------------|----------------------|-------------------------|------------------|
| 10/080,608                            | 02/21/2002      | Lee Makowski         | NANF.P-008              | 8580             |
| 21121                                 | 7590 06/25/2004 | •                    | EXAMINER                |                  |
| OPPEDAHL AND LARSON LLP               |                 |                      | MARSCHEL, ARDIN H       |                  |
| P O BOX 5068<br>DILLON, CO 80435-5068 |                 |                      | ART UNIT                | PAPER NUMBER     |
| 2122011,                              |                 | •                    | 1631                    | ·                |
|                                       |                 |                      | DATE MAILED: 06/25/2004 | 4                |

Please find below and/or attached an Office communication concerning this application or proceeding.

|  | Application No.  | Applicant(s)    |  |  |  |  |
|--|--|-----------------|--|--|--|--|
|  | 10/080,608   | MAKOWSKI ET AL. |  |  |  |  |
| Office Action Summary  | Examiner   | Art Unit        |  |  |  |  |
|  | Ardin Marschel   | 1631            |  |  |  |  |
| The MAILING DATE of this communication appears on the cover sheet with the correspondence address Period for Reply   |  |                 |  |  |  |  |
| A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.  - Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.  - If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.  - If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.  - Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b). |  |                 |  |  |  |  |
| Status   |  |                 |  |  |  |  |
| 1) Responsive to communication(s) filed on   |  |                 |  |  |  |  |
| •  | This action is <b>FINAL</b> . 2b)⊠ This action is non-final. |                 |  |  |  |  |
| 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under <i>Ex parte Quayle</i> , 1935 C.D. 11, 453 O.G. 213.   |  |                 |  |  |  |  |
| Disposition of Claims  |  |                 |  |  |  |  |
| 4) Claim(s) 1-178 is/are pending in the application.   |  |                 |  |  |  |  |
| 4a) Of the above claim(s) is/are withdrawn from consideration.   |  |                 |  |  |  |  |
| 5) Claim(s) is/are allowed.  |  |                 |  |  |  |  |
| 6) Claim(s) is/are rejected.   |  |                 |  |  |  |  |
| 7) Claim(s) is/are objected to.  |  |                 |  |  |  |  |
| 8) Claim(s) <u>1-178</u> are subject to restriction and/or   | election requirement.  |                 |  |  |  |  |
| Application Papers   |  |                 |  |  |  |  |
| 9) The specification is objected to by the Examiner.   |  |                 |  |  |  |  |
| 10) The drawing(s) filed on is/are: a) accepted or b) objected to by the Examiner.   |  |                 |  |  |  |  |
| Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  |  |                 |  |  |  |  |
| Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).   |  |                 |  |  |  |  |
| 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.   |  |                 |  |  |  |  |
| Priority under 35 U.S.C. § 119   |  |                 |  |  |  |  |
| 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f). a) All b) Some * c) None of:   |  |                 |  |  |  |  |
| 1. Certified copies of the priority documents have been received.  |  |                 |  |  |  |  |
| 2. Certified copies of the priority documents have been received in Application No   |  |                 |  |  |  |  |
| 3. Copies of the certified copies of the priority documents have been received in this National Stage  |  |                 |  |  |  |  |
| application from the International Bureau  | ` ''   |                 |  |  |  |  |
| * See the attached detailed Office action for a list of the certified copies not received.   |  |                 |  |  |  |  |
| Attachment(s)  |  |                 |  |  |  |  |
| 1) Notice of References Cited (PTO-892)  4) Interview Summary (PTO-413)  |  |                 |  |  |  |  |
| 2) Notice of Draftsperson's Patent Drawing Review (PTO-948) Paper No(s)/Mail Date.   |  |                 |  |  |  |  |
| 3) Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)  Paper No(s)/Mail Date  5) Notice of Informal Patent Application (PTO-152)  6) Other:   |  |                 |  |  |  |  |

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#### DETAILED ACTION

Restriction to one of the following inventions is required under 35 U.S.C. 121:

- I. Claims 1-19, 37-75, 113-131, and 149-164; drawn to a method for staged assembly of a nanostructure, classified in class 422, subclass 129. If this Group is elected then the below summarized FIVE specie elections are also required.
- II. Claims 20-36, 76-112, 132-148, and 165-178; drawn to a nanostructure assembly unit, classified in class 422, subclass 50. If this Group is elected then the below summarized FIVE specie elections are also required.

## FIRST SPECIE ELECTION REQUIREMENT FOR GROUPS I OR II:

This application contains claims directed to the following patentably distinct species of the claimed invention.

Specie A: Embodiments wherein specific non-covalent interactions are not required to be stabilized post-assembly as in instant claims other than claims 8 or 24

Specie B: Embodiments wherein specific non-covalent interactions are required to be stabilized post-assembly as in instant claims 8 or 24

The stabilization of chemical structures of significant complexity as instantly claimed via conversion to covalent linkages raises the added search burden over basic structure assembly of specificity of such conversion, completeness of conversion, and what is required for actual stabilization of such complex structures. Therefore an undue search burden would be required to search these species together vs. separate thus documenting the distinctness of these species.

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Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, claims 1-7, 9-19, 37-43, 45-75, 113-119, 121-131, 149-155, and 157-164 (Group I) and claims 20-23, 25-36, 76-79, 81-112, 132-135, 137-148, 165-168, and 170-178 (Group II) are generic to above species A and B.

Applicant is advised that a reply to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

### SECOND SPECIE ELECTION REQUIREMENT FOR GROUPS I OR II:

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This application contains claims directed to the following patentably distinct species of the claimed invention.

It is noted that independent claims 1 and 20 cite joining elements therein generically with generally specific joining element types listed in claims 13 and 30. Each of these joining elements types are limited via item (a)(iii) of claims 1 and item (c) of claim 20, but otherwise cover a broad spectrum of such elements. Each type of joining element as listed in claims 13 and 30 interact with other joining elements or a surface-bound nanostructure intermediate via distinct interactions which are specific regarding the binding interactions that they participate in. Such interactions are generally separately published and analyzed in the literature and are complex as most are biochemicals with their well known specific binding characteristics and conditions therefore. Thus, it would present an undue search burden to search these joining elements together. Applicants are required to elect a specific joining element type from claims 13 (Group I) or 30 (Group II), or, alternatively, may elect a generic joining element as reasonably included in the independent claims 1 or 20 which are not specified in either of claims 13 or 30.

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, claims 1-10, 12, and 15-18 (Group I) and claims 20-27, 29, and 32-35 (Group II) are generic to the above joining element types.

Applicant is advised that a reply to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims

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readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

# THIRD SPECIE ELECTION REQUIREMENT FOR GROUPS I OR II:

This application contains claims directed to the following patentably distinct species of the claimed invention.

It is noted that independent claims 1 and 20 cite an assembly unit therein generically with generally specific structural element types listed in claims 15-17 and 32-34. Each of these structural elements types cover a broad spectrum of such elements. Each type of structural element as listed in claims 15-17 and 32-34 interact with other elements via distinct interactions which are specific regarding the binding interactions

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that they participate in. Such interactions are generally separately published and analyzed in the literature and are complex as most are biochemicals with their well known specific binding characteristics and conditions therefore. Thus, it would present an undue search burden to search these structural elements together. Applicants are required to elect a specific structural element type from claims 15-17 (Group I) or 32-34 (Group II), or, alternatively, may elect a generic structural element as reasonably included in the independent claims 1 or 20 which are not specified in either of claims 15-17 or 32-34.

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, claims 1-14, 18, 19, 37-75, 113-131, and 149-164 (Group I) and claims 20-31, 35, 36, 76-112, 132-148, and 165-178 (Group II) are generic to the above structural element species.

Applicant is advised that a reply to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims

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are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

### FOURTH SPECIE ELECTION REQUIREMENT FOR GROUPS I OR II:

This application contains claims directed to the following patentably distinct species of the claimed invention.

It is noted that independent claims 1 and 20 cite an assembly unit therein generically without limitations as to any functional element types as required in claims 5 and 22 and specifically listed in claims 12 and 29. Each of these functional elements types cover a broad spectrum of such elements. Each type of functional element as listed in claims 12 and 29 interact with other elements via distinct interactions which are specific regarding the binding interactions that they participate in. Such interactions are generally separately published and analyzed in the literature and are complex as most are biochemicals with their well known specific binding characteristics and conditions therefore. Thus, it would present an undue search burden to search these functional elements together. Applicants are required to elect a specific functional element type from claims 12 (Group I) or 29 (Group II), or, alternatively, may elect a generic

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functional element as reasonably included in the independent claims 1 or 20 which are not specified in either of claims 12 or 29.

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, claims 1-11, 13-19, 37-47, 49-75, 113-123, 125-131, 149-159, 161, 163, and 164 (Group I) and claims 20-28, 30-36, 76-84, 86-112, 132-140, 142-148, 165-173, 175, 177, and 178 (Group II) are generic to the above functional element species.

Applicant is advised that a reply to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over

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the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

### FIFTH SPECIE ELECTION REQUIREMENT FOR GROUPS I OR II:

This application contains claims directed to the following patentably distinct species of the claimed invention.

Specie C: Embodiments wherein nanostructure capping is not required to be performed as in instant claims other than claims 3 or 27

Specie D: Embodiments wherein nanostructure capping is required to be performed as in instant claims 3 or 27

The capping of chemical structures of significant complexity as instantly claimed via at least one capping unit raises the added search burden over basic structure assembly of specificity of such capping linkage chemistry, completeness of capping, and what is required for actual effective capping of such complex structures. Therefore an undue search burden would be required to search these species together vs. separate thus documenting the distinctness of these species.

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, claims 1, 2, 4-19, 37, 38, 40-75, 113, 114, 116-131, 149, 150, and 152-164 (Group I) and claims 20-26, 28-36, 76-82, 84-112, 132-138, 140-148, 165-171, and 173-178 (Group II) are generic to species C and D.

Applicant is advised that a reply to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims

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readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

The inventions are distinct, each from the other because of reasons given above regarding species and regarding Groups I and II as follows:

The inventions of Group I and Group II are related as process of making and product made. The inventions are distinct if either or both of the following can be shown: (1) that the process as claimed can be used to make other and materially different product or (2) that the product as claimed can be made by another and materially different process (MPEP § 806.05(f)). In the instant case the product of Group II may be made by the materially different processes of either in-situ synthesis of

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joining elements such as peptide synthesis reactions, nucleic acid synthesis reactions, etc. or, alternatively, separate assembly of plural assembly units followed by further assembly of the assembly units to form a nanostruction of Group II.

Because these inventions are distinct for the reasons given above and have acquired a separate status in the art because of their recognized divergent subject matter, restriction for examination purposes as indicated is proper.

Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

The examiner has required restriction between product and process claims. Where applicant elects claims directed to the product, and a product claim is subsequently found allowable, withdrawn process claims that depend from or otherwise include all the limitations of the allowable product claim will be rejoined in accordance with the provisions of MPEP § 821.04. Process claims that depend from or otherwise include all the limitations of the patentable product will be entered as a matter of right if the amendment is presented prior to final rejection or allowance, whichever is earlier. Amendments submitted after final rejection are governed by 37 CFR 1.116; amendments submitted after allowance are governed by 37 CFR 1.312.

In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103, and 112. Until an elected product claim is found allowable, an otherwise proper restriction requirement between product claims

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and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowed product claim will not be rejoined. See "Guidance on Treatment of Product and Process Claims in light of In re Ochiai, In re Brouwer and 35 U.S.C. § 103(b)," 1184 O.G. 86 (March 26, 1996). Additionally, in order to retain the right to rejoinder in accordance with the above policy, Applicant is advised that the process claims should be amended during prosecution either to maintain dependency on the product claims or to otherwise include the limitations of the product claims. Failure to do so may result in a loss of the right to rejoinder. Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01.

Papers related to this application may be submitted to Technical Center 1600 by facsimile transmission. Papers should be faxed to Technical Center 1600 via the Central PTO Fax Center. The faxing of such papers must conform with the notices published in the Official Gazette, 1096 OG 30 (November 15, 1988), 1156 OG 61 (November 16, 1993), and 1157 OG 94 (December 28, 1993)(See 37 CFR § 1.6(d)). The Central PTO Fax Center number is (703) 872-9306.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ardin Marschel, Ph.D., whose telephone number is (571)272-0718. The examiner can normally be reached on Monday-Friday from 8 A.M. to 4 P.M.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Woodward, Ph.D., can be reached on (571)272-0722.

Any inquiry of a general nature or relating to the status of this application should be directed to Legal Instrument Examiner, Tina Plunkett, whose telephone number is (571)272-0549.

June 23, 2004

ARDIN H. MARSCHEL PRIMARY EXAMINER